Sunshine Is On the Way: Federal Reporting Law Proposed Rule

by William A. Mandell

The "Sunshine Law" provisions of the Affordable Care Act ("ACA")[1] establish the first ever national public reporting system of pharmaceutical and medical device company payments to physicians and teaching hospitals. This federal law preempts to a significant extent the Massachusetts gift ban/public reporting law.[2] The exact level of pre-emption, however, cannot be known until final regulations are promulgated under the Sunshine Law.

The United States Centers for Medicare and Medicaid Services ("CMS") proposed rule to implement the Sunshine Law[3] does shed some more light on the scope of this national reporting system and its preemptive effect. Nevertheless, CMS is still undergoing an extensive process of soliciting public comments on how best to implement the federal reporting system within the parameters established by Congress. This is clearly a massive undertaking, and as summarized below, the Proposed Rule leaves much to be determined at a later point by CMS.

Overview of the Sunshine Law

The Sunshine Law establishes U.S. policy on the regulation of the independence of clinical, academic and research activities in medicine and conflicts of interest arising from industry financial relationships. This policy does not limit physician and hospital relationships with pharmaceutical, device and biotech companies beyond the limits already imposed by existing federal fraud and abuse laws, such as the anti-kickback statute.[4] It is intended to use the transparency of public disclosure, via a national searchable database, to expose those financial relationships – regardless of their compliance with legal and ethical standards - to the light of day.

The Sunshine Law requires payments or transfers of $10 or more[5] made by pharmaceutical, medical device and biotechnology manufacturers operating in the U.S. or its territories to physicians[6] or teaching hospitals to be tracked and reported to the United States Department of Health and Human Services ("HHS"). In addition, the Sunshine Law requires tracking and reporting to HHS payments and other transfers to physicians (or their designees) who have an ownership or interest in Group Purchasing Organizations ("GPOs").

ACA mandates that the reported information, identifying the recipient, amount, and nature of each payment, become part of an on-line searchable and downloadable public database to "go live" on September 30, 2013.

Based on the Proposed Rule, here is a summary of what is certain (and what is still to be determined) about the scope of mandatory reporting and its preemptive impact on existing state laws, such as the Massachusetts Gift Ban and reporting law.

Who Has to Track and Report Data?

The Proposed Rule defines "applicable manufacturer" very broadly to include any company which operates in the United States, or a U.S. territory, possession, or commonwealth, and is engaged in the production, preparation, propagation, compounding, or conversion of a drug, device, biological, or medical supply that is reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program.

This broad definition would subject companies that are located and/or produce products outside of the U.S. to the reporting requirements if they sell just one product that is reimbursable under the federal programs in the U.S.

CMS is also covering any company under "common ownership" that assists a manufacturer in the distribution or marketing of a drug or device, but has not expanded the mandate to independent distributors or marketing companies.[7]

What Transactions Must be Reported Under the Sunshine Act?

Under the Sunshine Law and the Proposed Rule, covered manufacturers will be required to track and report to HHS the following information for each reportable

payment or transfer on an annual basis:

(1) The recipient's name.

(2) The business address of the recipient and, if the recipient is a physician, his or her specialty and National Provider Identifier ("NPI").

(3) If the company is aware that the payment will be indirectly provided to a physician, the name of the entity physician.

(4) The amount of the payment or other transfer.

(5) The date on which the payment or other transfer was provided.

(6) A description of the form of the payment or other transfer.

(a) cash or a cash equivalent;
(b) in-kind items or services; or,
(c) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Although the Sunshine Law authorized HHS to establish other forms of payment to be reported, CMS did not add any forms of payment in the Proposed Rule beyond those outlined in the statute because it believes what is provided in the statute is sufficient to describe payments and other transfers of value. However, CMS asked for comments on whether other categories are necessary or would be helpful. CMS's apparent intent to stick to the statute's scope of required information about each reportable payment is a welcome development.

The nature of the payment or other transfer of value must also be disclosed as:

(a) consulting fees;
(b) compensation for services other than consulting;
(c) honoraria;
(d) gifts;
(e) entertainment;
(f) food;
(g) travel (including the specified destinations);
(h) education;
(i) research;
(j) charitable contribution, defined by CMS to be those made to a Section 501(c)(3) organization;
(k) royalties or licenses;
(l) current or prospective ownership or investment interest;
(m) direct compensation for serving as faculty or as a speaker for a medical education program;
(n) grant; or
(o) any other categories to be later designated by HHS.

CMS proposed that each payment or transfer be reported separately, but asked for public comment on whether aggregated reporting could be used. It will be helpful if CMS can provide in the final rule further explanation and details on what it intends to be captured by requiring disclosure of "prospective" ownership or investment interests.

As to food, CMS wants manufacturers to take the total amount of the food provided to medical groups at their offices and divide it by the number of physicians in the group and require a report on each physician, even if some of the group physicians did not come to the meeting and/or partake of the meal. Thus a food spread worth $30 provided by a drug company representative to a practice with three doctors would result in a Sunshine Law report of a $10 food item being given to each of the three physicians under CMS's proposed reporting rules even if only one of them actually attended the meeting and ate.

Such an approach could result in a very extensive and costly internal tracking mandate for reporting companies, and more extensive disclosures and listings for physicians, especially those in larger groups that have more frequent visits by company representatives where food is supplied. This approach would also make it impossible for physicians who elect not to partake in company programs and food offerings to avoid public listing as a recipient of company-provided meals. This does not seem to be a fair and equitable way to achieve accurate public reporting.

Payments and transfers not provided to a physician directly are still reportable if the company was aware that the payment will be indirectly provided to the physician, CMS suggests that the "awareness" standard should be based on the Federal False Claims Act standard. This would apparently trigger a reporting requirement if the company, or its employees or agents, knew or should have known a payment would be provided indirectly to the physician. This indirect reporting standard may open up to public disclosure payments made by companies to health care facilities, medical schools, group practices, and CME companies that may in some way be used to help underwrite the activities of particular physicians in

their clinical and research and teaching activities.

The Sunshine Law will also require disclosure of the name of the drug, device, biological, or medical supply if the reportable payment or other transfer of value is related to marketing, education, research specific to a covered drug, device, biological, or medical supply.

CMS proposed that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported as required under the Sunshine Law regardless of whether the particular payment or other transfer of value "is associated" with a covered drug, device, biological, or medical supply. CMS did not provide any meaningful guidance or explanation as to what point a payment or transfer is sufficiently "associated" with a product to trigger a required report.

Also, in the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient (e.g., a payment made to a charitable disease organization at the request of a physician), the applicable manufacturer would be required to disclose that payment or other transfer of value under the name of the covered recipient.

To What Extent Will State Laws Regulating Industry Financial Transactions and Reporting Be Pre-Empted?

The federal Sunshine Law preempts any state statute or regulation that requires any entity that meets the federal definition of "manufacturer" to disclose or report, in any format, the type of information reportable to HHS regarding payments or other transfers of value to physicians or teaching hospitals worth over $10.

Under the Sunshine Law, any state law that requires manufacturers to disclose or report the same type of information that is reportable to HHS is preempted. It does not preempt any state laws that require the disclosure or reporting of information that is not reportable under the Sunshine Law database or that cover a broader category of reporting parties or recipients than defined under the ACA and the CMS Rule.

Based on the ACA and the Proposed Rule, the Massachusetts law will be preempted only to the extent that the Massachusetts law requires tracking and reporting of "sales and marketing activity"[8] interactions with Massachusetts physicians or teaching hospitals that are reportable to HHS under the Sunshine Law.

The Sunshine Law does not preempt any state laws that require the reporting of information that is exempt or not subject to reporting under the federal law. Thus, the Massachusetts reporting system can continue to require the reporting of:

- Sales and marketing activity from independent distributors that take title (as opposed to consignment) to products;

- Sales and marketing activities with non-physician licensees who are authorized to prescribe, as well as with non-teaching hospitals, nursing homes and pharmacists;

- Sales and marketing activities that are exempt from the Sunshine Law[9] – but the interplay between activities that are exempt from Sunshine but still reportable to DPH are not exact and require careful analysis.

Furthermore, there is no preemption of state laws that require reporting to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

The Sunshine Law and CMS Proposed Rule do not alter the duty of manufacturers and distributors, subject to the Massachusetts law, to adopt and comply with a compliance program and a Marketing Code of Conduct that conforms to the DPH regulations, 105 CMR 970.000,[10] and annually submit compliance plan information and certifications to DPH.

Massachusetts, and other states, will continue to be able to pass state laws prohibiting and regulating interactions between industry and health care providers that do not involve governmental or public disclosure without any level of federal preemption.

The Massachusetts limits on company gift-giving to physicians – which is not a total gift ban as it permits certain educational items worth less than $100 – or the Massachusetts requirements for permissible consulting and other service relationships will not preempted. The Massachusetts law is more than a "gift

ban." It requires drug and device manufacturers and distributors to enact and follow a stringent compliance plan and code of conduct covering financial interactions with physicians and other prescribing health professionals.

The reporting system under the Massachusetts law will be dramatically preempted by the Sunshine Law. The DPH public database, which has been operational since 2010, does require reporting of financial transactions that substantially overlap with those also required to be reported under the Sunshine Law. The preempted transactions appear to be those that come within the definition of "sales and marketing activities" under the DPH regulations that are made to Massachusetts licensed physicians, dentists, podiatrists, optometrists or chiropractors. Payments or items of value worth $50 or more made to other Massachusetts licensees who can prescribe would not be preempted.

On December 28, 2011 DPH did issue a guidance letter to Pharmaceutical and Medical Device Manufacturers in reaction to the CMS Proposed Rule. In the letter DPH acknowledges the Sunshine Law's inevitable pre-emptive effect on Chapter 111N and its own regulations that require "the collection and reporting of the same data elements . . ." as the Sunshine Law. Noting the CMS delay under the Proposed Rule of the effective date for the collection and reporting of data under the Sunshine Law, DPH stated in relevant part that:

> Until CMS publishes a final rule and certain Massachusetts requirements are preempted, pharmaceutical and medical device manufacturing companies must continue to collect and submit disclosures on all covered recipients as currently defined under the law, including physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, all hospitals, nursing homes, and all other purchasers, prescribers, or dispensers of drugs, biologics, or medical devices.[11]

DPH further noted in this letter that all other requirements under 105 CMR 970.000 remain in effect, and that the annual registration requirement and associated fee submitted to DPH and the annual self-audit will not be pre-empted by the Sunshine Act. Furthermore, DPH confirmed that the mandatory marketing Code of Conduct established under Chapter 111N and 105 CMR 970.000 "remains in effect and will not be altered by federal preemption."[12]

Thus, DPH has confirmed that it intends to continue to impose the annual fee of $2,000 on companies that are subject to the reporting obligations under Massachusetts law, whether they actually file any reports to DPH or not.

How Does the Sunshine Law Treat Research Differently Than the Massachusetts Law?

The possible preemption and differing approaches toward research relationships is of great importance to Massachusetts health lawyers due to the prevalence of teaching hospitals, research centers and product development in Massachusetts. Under the current Massachusetts reporting system, DPH exempts otherwise reportable financial relationships if they involve clinical trials[13] or genuine research.[14] The Sunshine Law does not exempt research related relationships from tracking and disclosure.

Thus, manufacturers will be required to track and report to HHS any payment or transfer of value worth $10 or more related to research or pre-market approval activities. However, such reported interactions do not immediately become public. Information submitted to HHS with respect to a payment or other transfer of value made pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology; or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply; or in connection with a clinical investigation regarding a new drug, device, biological, or medical supply; is reportable to HHS annually, but will not be made immediately available on the public database.

Under the Sunshine Law such research-related payments and transfers of value become public on the earlier of the FDA approval date, or four calendar years after the date such payment or other transfer of value was made. During the non-public phase of such reported data, the information in the hands of HHS is not subject to the Freedom of Information Act.

CMS's proposal limits reportable research-related payments to bona fide research activities,

including clinical investigations that are subject to a written agreement between the applicable manufacturer and the organization conducting the research, as well as a research protocol.

The Proposed Rule also addresses indirect research payments, including those made by a manufacturer (or a contract research organization on its behalf) to a clinic, hospital or other research institution, which in turn pays one or more physicians to act as principal investigator(s). Such indirect research payments are reportable under the principal investigator's name and NPI, and CMS has proposed that both indirect and direct payments be reported in the aggregate, but to avoid any misleading public information is suggesting it will not include indirect research payments under the physician's public database listing.

It must be questioned whether the Sunshine Law's research reporting requirements (that go beyond Massachusetts obligations under Chapter 111N) could undermine the collaboration of industry and academia, as many teaching hospitals and faculty may steer away from arrangements that may become public. Clearly, the possible undesired side effects of the Sunshine Law's mandate on public disclosure of research funding should be tracked to see if this new law has any deleterious effect on bio-technical research and medical innovation.

CMS is seeking further comment and hopefully it will clarify how and to what extent reported research payments will be publicly disclosed.

What Else Has CMS Told Us Under the Proposed Sunshine Rule?

The deadlines to start tracking transactions and filing reports to CMS for 2012 payments and transfers are likely to be changed. CMS is seeking comment on whether the March 31, 2013 reporting deadline established in the statute is still feasible given that the final rule may not be issued until the later part of 2012.

The delay by CMS in issuing Sunshine Law regulations has also impacted the date when companies must start tracking their interactions with health care providers for ultimate reporting. While the Sunshine Law requires certain manufacturers and group purchasing organizations ("GPOs") to start collecting reportable information as of January 1, 2012, the commencement date has now been delayed due to the late arrival of the CMS Proposed Rule. In the Proposed Rule, CMS granted manufacturers, distributors and GPOs a reprieve from starting their mandated data collection efforts until 90 days after the publication of the final CMS Rule, expected sometime later in 2012.

The Sunshine Law grants reporting companies and recipients an opportunity to review and submit corrections to the information submitted for at least 45 days prior to such information being made available to the public. CMS has proposed that this 45 day period for reporting entities and physicians to review submitted reports for errors prior to its public release can cover both current and previous year data. For data disputed by a physician, CMS suggests that the physician directly contact the reporting company to first try to reconcile the dispute. If the dispute cannot be resolved within the 45 day period, CMS further suggests in the Proposed Rule that both versions of the disputed information be made available on the public website. While the final rule should have a more definitive process for handling disputed information, CMS has made clear that it does not intend to try to arbitrate any such disputes between reporting manufacturers, GPOs and physicians.

CMS has not fully explained how it will provide for prior review effectively and accurately in this short time period in view of the enormous number of hospitals and physicians who may dispute information in the public database. CMS will need to adopt a notational or rebuttal process much like is used with the National Practitioner Data Bank, in which both company and recipient get to post their version of the facts.

Who Could Find Themselves Named in the Database as Recipients?

The CMS Proposed Rule follows the Sunshine Law definition of "physician" and includes any medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist or chiropractor who is legally authorized to render services within the scope of his or her license.

"Teaching hospital" (which had not been defined in the Sunshine Law) is defined in the Proposed Rule as any hospital that receives direct Graduate Medical Education ("GME") payments or indirect Graduate Medical Education ("IME") payments. This

definition, if finally adopted, will exempt payments and transfers to any hospital that may have an accredited residency program but does not receive any GME or IME Medicare payments. CMS is seeking public comment on its definition of "teaching hospital" so changes to the scope of the definition could be in store for the final rule.

Summary

As has been the experience with other CMS rules on the regulation of physician financial relationships, such as the Stark law, the agency's deliberate approach will result in many lingering questions on the timing and scope of this mandate.

In the most extreme scenario though, tracking and reporting will commence sometime in 2012, meaning that companies and recipients subject to the Sunshine Law need to immediately start the process of establishing and/or modifying and enhancing their tracking systems.

As the possible repeal of ACA will be heard by the Supreme Court sometime later this term, it is still not clear whether the Sunshine Law could be struck down if the Court rules that the ACA is unconstitutional.[15] Until the Supreme Court case reviewing the constitutionality of the ACA is decided and CMS issues final and more detailed rules giving manufacturers, distributors, physicians, and hospitals more details on the Sunshine Law requirements, the full scope and cost of this massive national mandate is still significantly unknown.

CMS should ensure that the final Sunshine Law Rule completely addresses the open questions identified above, and confirms the exact scope of preemption, so that states like Massachusetts that have chosen to regulate this area can be clear on which parts of their state's laws will no longer be in effect.

(Endnotes)
1 42 U.S.C. §1128G (Section 1128G of the Social Security Act), added by Section 6002 of the Affordable Care Act (signed into law on March 23, 2010) entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests."
2 Massachusetts General Law, Chapter 111N and implementing agency rules, DPH regulations 105 CMR 970.000.
3 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (Dec. 19, 2011).
4 42 U.S.C. §1320a–7b (Section 1128B(b) of the Social Security Act).
5 Transfers of value worth less than $10 are not reportable unless the aggregate amount transferred to, requested by, or designated on behalf of the recipient by the manufacturer during a calendar year exceeds $100. These thresholds will be increased annually by the CPI.
6 The law references the definition of physicians found in 42 U.S.C. §1395x(r), which includes dental surgeons, podiatrists, optometrists, chiropractors as well as physicians.
7 "Common ownership" would be defined by CMS as the same individual, individuals, entity, or entities, directly or indirectly, owning any portion of two or more entities. The common ownership definition would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations. It is also soliciting comments on whether to limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. CMS is also suggesting that companies under common ownership that each meet the definition of manufacturer must report separately but any other companies under common ownership that are subject to the reporting obligation could choose to report separately or together.
8 "Sales and marketing activity" is defined under 105 CMR 970.004 as sales and marketing activities including "advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force ... [as well as] any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose."
9 The Sunshine Law exempts from reporting the following:
- Payments or other transfers of value less than $10 (unless the aggregate amount paid or transferred by a reporting company to the recipient exceeds $100 per calendar year).
- Product samples that are not intended to be sold and are intended for patient use (although there will a separate non-public database).
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an

administrative proceeding.
10 The Massachusetts mandated Marketing Code of Conduct in many respects is more stringent than the standards set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009 and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009. The Massachusetts mandated Marketing Code of Conduct also requires CME programs to adhere to the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support (even if ACCME accreditation is not secured).
11 See, http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pcoc/ma-pharm-code-of-conduct-circular-letter-12-28-2011.pdf.
12 Id.
13 105 CMR 970.009 states that reportable "sales and marketing activity does not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or 'new use' or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. "Clinical trial," is defined by 105 CMR 970.004 as "a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency."
14 "Genuine Research Project" is defined under 105 CMR 970.004 as "a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry."
15 The Supreme Court has agreed to hear appeals from a case in which the United States Court of Appeals for the 11th Circuit struck down the individual mandate to purchase health insurance in the ACA. See, *State of Florida, et al. v. U.S. Dep't of Health & Human Services., et al.,* Nos. 11-11021 & 11-11067 (11th Cir., Aug. 12, 2011), available at http://www.uscourts.gov/uscourts/courts/ca11/201111021.pdf. In taking the appeal, the Supreme Court has agreed to decide not only whether the mandate is constitutional but also, if it is not, how much of the balance of the ACA must be struck down as well.